K081089

Kimberly-Clark Corporation

JUL 14 2008

Traditional 510(k) for Kimberly-Clark* STERLING* Nitrile & STERLING* Nitrile-Xtra* Powder-Free Exam Gloves with a Chemotherapy Drug Use Claim

Section 5. 510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Submitter's Name:	Kimberly-Clark Corporation
Submitter's Address:	1400 Holcomb Bridge Road Roswell, GA 30076-2199
Submitter's Phone No:	770-587-8208
Submitter's Fax No.	920-969-5160
Date of Preparation:	July 10, 2008
Name of Device Trade Name: Common Name: Classification Name:	 • Kimberly-Clark* STERLING* Nitrile Powder-Free Exam Glove with a Chemotherapy Drug Use Claim • Kimberly-Clark* STERLING* Nitrile-Xtra* Powder-Free Exam Glove with a Chemotherapy Drug Use Claim Patient examination glove Glove, Patient Examination, Specialty – 80 LZC
Legally marketed device to which equivalency is claimed:	• Kimberly-Clark* STERLING* Nitrile Powder-Free Exam Glove - K051347 • Perusahaan Getah Asas Sdn. Bhd. Powdered Free Patient Examination Gloves, Blue Colored Non-Sterile (Low Dermatitus Potential and Chemotherapy Drug Protection Labeling Claims) – K042805
Description of the device:	Light gray nitrile, chlorinated, powder-free, textured fingertip, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*
Intended use of device:	The Kimberly-Clark* STERLING* Nitrile and Nitrile-Xtra* Powder-Free Exam Gloves are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.

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<table>
<tr><td>Summary of technological characteristics compared to predicate device:</td><td colspan="3">There are no different technological characteristics compared to the predicate devices. They are all powder-free non-sterile nitrile exam gloves, one predicate a gray color and the other a blue color. The Chemotherapy Drug Use Claim is similar to that of Perusahaan Getah Asas Sdn. Bhd. Powdered Free Patient Examination Gloves, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claims) – K042805</td></tr>
<tr><td rowspan="15">Brief description of Non-Clinical Tests:</td><td>Non-Clinical Tests</td><td>Standard</td><td>Performance</td></tr>
<tr><td>Dimensions</td><td>ASTM D 6319-00a</td><td>Meets</td></tr>
<tr><td>Physical Properties</td><td>ASTM D 6319-00a</td><td>Meets</td></tr>
<tr><td>Freedom from pinholes</td><td>ASTM D 6319-00a
ASTM D 5151-06</td><td>Meets
Meets</td></tr>
<tr><td>Powder Free</td><td>ASTM D 6124-06
ASTM D 6319-00a</td><td>Meets
Meets</td></tr>
<tr><td>ISO Skin Irritation Study</td><td>ISO 10993, Part 10</td><td>Meets</td></tr>
<tr><td>Murine Local Lymph Node Assay</td><td>ISO 10993, Part 10</td><td>Meets</td></tr>
<tr><td>ISO Systemic Toxicity Study</td><td>ISO 10993, Part 11</td><td>Meets</td></tr>
<tr><td>Resistance to Permeation (Protective Clothing)</td><td>ASTM F 739-07</td><td>See data below</td></tr>
<tr><td>Resistance to Permeation (Medical Gloves)</td><td>ASTM D 6978-05</td><td>See data below</td></tr>
<tr><td>Tested Chemotherapy Drug and Concentration</td><td colspan="2">Average Breakthrough Detection Time (minutes)</td></tr>
<tr><td>Cyclophosphamide (20.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Doxorubicin HCl (2.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Etoposide (20.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>5-Fluorouracil (50.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Paclitaxel (Taxol) 6.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>ThioTEPA (10.0 mg/ml)</td><td colspan="2">Avg. minutes before breakthrough = 54.2</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Dacarbazine (10.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Ifosfamide (50.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Mitoxantrone (2.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Vincristine sulfate (1.0 mg/ml)</td><td colspan="2">No breakthrough up to 240 minutes</td></tr>
<tr><td>Brief description of Clinical Tests:</td><td colspan="3">No new clinical tests were required to support this 510(k) application.</td></tr>
<tr><td>Conclusions drawn from the Non-Clinical and Clinical Tests:</td><td colspan="3">Non-clinical laboratory and animal based biocompatibility test data confirm the Kimberly-Clark* STERLING* Nitrile and Nitrile-Xtra* Powder-Free Exam Gloves Kimberly-Clark* STERLING* meets all applicable performance and biocompatibility requirements.</td></tr>
<tr><td>Other Information deemed necessary by the FDA:</td><td colspan="3">None</td></tr>
</table>

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2008

Mr. Richard V. Wolfe
Associate Director, Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K081089
Trade/Device Name: Kimberly-Clark* STERLING* Nitrile and STERLING* Nitrile-Xtra* Powder-Free Exam Gloves with a Chemotherapy Drug Use Claim
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC
Dated: June 27, 2008
Received: July 2, 2008

Dear Mr. Wolfe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-***[See Below For Phone Numbers]***. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Kimberly-Clark Corporation

INDICATIONS FOR USE

Applicant: **Kimberly-Clark Corporation**

510(k) Number: **K081089**

Device Name: Kimberly-Clark* STERLING* Nitrile and STERLING* Nitrile-Xtra* Powder-Free Exam Gloves with a Chemotherapy Drug Use Claim

Indications for Use: Based upon 21CFR§880.6250 "Patient examination glove"

A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter ___X___
Per 21CFR 801.109 Subpart D Per 21CFR 801.109 Subpart C

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081089